**OKLAHOMA DEPARTMENT OF AGRICULTURE,
FOOD, AND FORESTRY**
MEAT AND POULTRY INSPECTION SERVICE
OKLAHOMA CITY, OK

# MPI NOTICE	403	1/15/13

ODAFF MPI VERIFICATION TESTING FOR NON-O157 SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (NON-O157 STEC) UNDER RAW BEEF SAMPLING PROGRAMS

I. PURPOSE

A. This notice provides instructions to inspection program personnel (IPP) that establishments will be required to reassess their HACCP systems in response to ODAFF MPI or establishment non-O157 STEC positive test results, if they have not already addressed the hazard in their HACCP system.

B. This notice also provides instructions to IPP that establishments which produce raw ground beef products will need to begin taking steps to address non-O157 STECs in their HACCP systems and performing activities to gather data to validate that their food safety systems are adequately designed to control non-O157 STECs. If they have not already done so establishments will be required to reassess their HACCP system in response to non-O157 STECs within 90 days of the implementation of this notice.

C. This notice provides IPP with information on non-O157 Shiga toxin-producing *Escherichia coli* (STEC) laboratory tests that will be performed on samples of raw ground beef collected under existing *Escherichia coli* (*E. coli)* O157:H7 verification sampling programs. ODAFF MPI will test raw ground beef for the six relevant non-O157 STEC serogroups (O26, O45, O103, O111, O121, and O145) in addition to *E. coli* O157:H7.

II. REFERENCES

2 O.S, §§ 6-181 et seq.
76 Federal Register 58157
9 CFR 417.3(a) and (b)
FSIS Directives 5100.1, Attachment 1; 6410.1; 10,010.1 Chapters III, IV, and VI; and 10010.3, Revision 3
OK MPI Notices 601, Revision 1; 602, Revision 1; 603 Revision 1; 604, Revision 1; 605, Revision 1; and 607, Revision 1

III. BACKGROUND

Because of the public health concern regarding the non-O157 STEC serogroups, in

2011, FSIS announced to the public in a *Federal Register* notice its intent to declare at least six non-O157 STECs (O26, O45, O103, O111, O121, and O145) adulterants in non-intact raw beef products and product components (http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023.pdf).
ODAFF MPI has been screening all raw ground beef samples for non-O157 STECs since 2010.

Following the initial 90 days of the implementation of this notice, additional instructions will be provided that will address for-cause FSAs in response to positive non-O157 STEC results, and the adequacy of an establishment's HACCP system contols and supporting documentation concerning adulterant STECs during routine and for-cause FSAs.

IV. IPP RESPONSIBILITIES FOR ESTABLISHMENT AWARENESS MEETING

IPP are to discuss non-O157 STEC testing with establishment personnel during the next weekly meeting and document the meeting in a Memorandum of Interview (MOI). IPP are to share the following information with the establishment:

1. Samples of raw ground beef that are collected under sampling programs will be tested by ODAFF MPI for non-O157 STECs as well as *E. coli* O157:H7.

2. ODAFF MPI does not expect establishments to reassess their HACCP plans because of non-O157 STEC testing implementation. No noncompliances (NRs) or Food Safety Assessments (FSAs) will result should an establishment not reassess its HACCP plan.

3. Background information is in Attachment 1.

4. ODAFF MPI recognizes that establishments will begin taking steps to address non-O157 STECs in their HACCP systems and performing activities to gather data to validate that their food safety systems are adequately designed to control non-O157 STECs. Establishments are to document and identify in their initial validation activity plans the time frame in which they will have accumulated sufficient data to conclude that their food safety systems are demonstrated to be adequate to control for the relevant non-O157 STECs. IPP are to verify that establishments are adhering to the controls that they identified in their food safety systems. ODAFF MPI recognizes that establishments may initially or permanently modify their Certificates of Analysis (COA) and Letters of Guarantee (LOG) to identify that the relevant non-O157 STECs are being controlled using the same controls as for *E. coli* O157:H7.

5. When ODAFF MPI finds a raw ground beef sample positive for any of the relevant non-O157 STEC, the Agency's actions will be consistent with its actions in response to *E. coli* O157:H7 positive results (see Section VI below), including performing follow-up sampling as described in Directive 10,010.3, Revision 3.

V. IPP RESPONSIBILITIES FOR COLLECTING AND SUBMITTING SAMPLES

When IPP receive a sample request for raw ground beef products, they are to continue to follow the instructions in OK MPI Notices 601, Revision 1; 602, Revision 1; 603, Revision 1: 604, Revision 1; and 605, Revision 1 for collecting samples. There are no changes to product sampling eligibility or sample collection procedures for the raw ground beef sampling programs.

VI. IPP AND EIAO ACTIONS FOLLOWING A POSITIVE ODAFF TEST RESULT

A. IPP are to follow the same actions for each non-O157 STEC analysis positive result as outlined in FSIS Directive 10,010.1, Chapter III, as they do for *E. coli* O157:H7, with the following changes:

1. IPP are to assess the sanitary dressing procedures and process controls that cattle slaughter establishments employ in their food safety systems, in the manner described in FSIS Directive 6410.1. Such controls are likely to include decontamination and antimicrobial intervention treatments. IPP are to especially focus on how the establishment is preventing visible contamination on the carcass at all stages of the hide removal process, not just after the hide is completely removed.

2. When verifying adequate corrective actions, IPP are first to determine whether the establishment identified non-O157 STEC as a hazard in its hazard analysis. If the establishment identified non-O157 STEC, IPP are to verify that the establishment takes corrective action in accordance with 9 CFR 417.3(a). If the establishment did not identify non-O157 STEC in its hazard analysis, IPP are to verify that the establishment takes corrective action in accordance with 9 CFR 417.3(b). When verifying compliance with 9 CFR 417.3(b), IPP are not to expect the establishment to initiate a testing program for non-O157 STECs if it does not already have one at this time. Additionally, when verifying compliance with 9 CFR 417.3(b), IPP are not to expect the establishment to perform reassessment for the first 90 days after the implementation of this notice. Beginning 90 days after the implementation of this notice, when verifying compliance with 9 CFR 417.3(b), IPP are to verify that the establishment has reassessed its HACCP system for non-O157 STEC or maintains support demonstrating that its existing controls for *E. coli* O157:H7 effectively control the non-O157 STEC. When an establishment takes corrective actions in accordance with 9 CFR 417.3(b), IPP are to evaluate whether the establishment properly implemented existing controls and sanitary dressing procedures.

B. Enforcement, Investigations and Analysis Officers (EIAOs) are to follow the same instructions for each non-O157 STEC analysis positive result as outlined in FSIS Directive 10,010.1, Chapter III, as they do for *E. coli* O157:H7, with the exception that a for-cause FSA would not be scheduled.

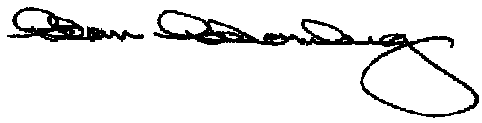
VII. IPP AND EIAO RESPONSIBILITIES RELATED TO AN ESTABLISHMENT'S CONTROLS FOR *E. coli* O157:H7 and Non-O157 STEC

A. ODAFF MPI will not require establishments to adjust their existing testing programs for non-O157 STEC. Establishments are also not required to automatically implement additional specific requirements in their COAs, antimicrobial interventions, or other process controls specifically for the six non-O157 STECs. Establishments that produce non-intact raw beef products, such as ground beef, or the intact raw components of those products, typically operate HACCP systems that address *E. coli* O157:H7, and, as a result, many have already incorporated antimicrobial interventions, such as organic acid sprays, into their processing.

B. IPP are not to expect establishments to reassess their HACCP plans because of non-O157 STEC testing implementation, and IPP are not to issue an NR, nor is an FSA to be conducted should an establishment not reassess its HACCP plan.

C. When IPP review records as described in FSIS Directive 10,010.1, Chapter IV, and FSIS Directive 5000.2, IPP are to review such records for any non-O157 STEC testing the establishment is conducting in addition to any *E. coli* O157:H7 testing.

D. EIAOs are to review supporting documentation that the establishment has for its sampling and testing programs, as described in FSIS Directive 10,010.1, Chapter VI, as part of a Raw, Non-intact HACCP verification task (for raw ground beef or patty sampling). Supporting documentation may include information regarding the establishment's test method compared to the FSIS test method (refer to FSIS Directive 5100.1, Attachment 1 for guidance). An example of such documentation includes referring to a test method reviewed by FSIS, and for which FSIS has issued a "letter of no objection," and verifying that the establishment is following the parameters for test use as stated in the "letter of no objection." When performing a routine or "for-cause" (for reasons other than non-O157 STEC) FSA in an establishment producing beef manufacturing trimmings, EIAOs are to review and assess supporting documentation and establishment decision-making regarding non-O157 STECs and are to document this information in the FSA, but they are not to recommend issuing any NRs .



Stan Stromberg
Director, Food Safety Division

DISTRIBUTION **SUBJECT CATEGORY**

All MPI Personnel **HACCP/SSOP**
Attachment 1

Background on FSIS non-O157 STEC Testing

The Centers for Disease Control and Prevention (CDC) estimates that there are approximately 175,905 domestically acquired foodborne illnesses associated with all Shiga toxin-producing *E. coli* (STEC) annually (Scallan et al, 2011)[1]. *E. coli* O157:H7 is the most well known STEC and, according to the CDC, annually is responsible for approximately 63,153 (36%) of the domestically acquired foodborne STEC illnesses. The remainder of the illnesses associated with STEC (112,752 or 64%) are caused by non-O157 STEC. While more than 50 non-O157 STEC serogroups have been associated with human illness, 70 to 80 percent of confirmed non-O157 STEC illnesses are caused by six STEC serogroups – O26, O45, O103, O111, O121, and O145. These illnesses can be equivalent in severity to those caused by *E. coli* O157:H7. In the U.S, at least one outbreak and several sporadic illnesses from non-O157 STEC serogroups have been associated with ground beef products.

Because of the public health concern regarding the non-O157 STEC serogroups, in 2011, FSIS announced to the public in a *Federal Register* notice its intent to declare at least six non-O157 STECs (O26, O45, O103, O111, O121, and O145) adulterants in non-intact raw beef products and product components (http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023.pdf) On June 4, 2012, FSIS will begin testing beef manufacturing trimmings from cattle slaughtered on-site on or after June 4, 2012 for the six non-O157 STEC in addition to *E. coli* O157:H7. To provide establishments time to comply with the new policy, FSIS announced that beef manufacturing trimmings collected from cattle slaughtered on-site before June 4, 2012 will be analyzed for *E. coli* O157:H7 only (http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0023N.pdf) At a later date, FSIS laboratories will implement non-O157 STEC testing in other sampling programs

Non-O157 STEC testing results

FSIS, together with the Agricultural Research Service (ARS), has developed a laboratory method for detection and isolation of non-O157 STEC serogroups from raw beef. Further information regarding the current laboratory method is available on the FSIS website, at
http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp
The FSIS methods for non-O157 STEC and *E. coli* O157:H7 differ, but both have similar stages when results are communicated by the laboratory (e.g., potential, presumptive, confirmed). Table 1 shows a side-by-side comparison of the non-O157 and *E. coli* O157:H7 stages for reporting results.

One difference between these two methods identified in Table 1 is that testing for non-O157 STEC involves a two-stage polymerase-chain-reaction (PCR) screening test, while the methodology for *E. coli* O157:H7 only includes a single-stage PCR screening

[1] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, and Griffin PM. 2011. Foodborne illness acquired in the United States – major pathogens. Emerg Infect Dis. 17(1):7-15.

test. In the non-O157 STEC screening test, the first stage will detect samples positive for the genes *stx* (Shiga toxin) and *eae* (intimin). In the second stage, samples will be screened for the presence of one of the six target serogroups (O26, O45, O103, O111, O121, and O145). Both these PCRs are performed at the same time. A sample will be identified as ‘‘potential positive’’ when it tests positive for the *stx* gene and the *eae* gene and is also positive for one or more of the target serogroup genes. Samples identified as “potential positive” will continue through further testing to confirm whether they are positive for one or more of the six non-O157 STEC. Only samples that are confirmed positive for one of the six non-O157 STEC or that are confirmed positive for *E. coli* O157:H7 will be considered adulterated.

Table 1. Comparison between non-O157 STEC and *E. coli* O157:H7 Testing

Stage	non-O157	*E. coli* O157:H7
Potential	Sample that causes a positive reaction with both screen tests: • stage 1 - for the *stx* and the *eae* genes and • stage 2 (concurrent with stage 1) for one or more of the target serogroup genes	Sample that causes a positive reaction with the screen test
Presumptive	Sample that has typical colonies, observed on Rainbow Agar, and reacts specifically with one or more of the target serogroup antiserum	Sample that has typical colonies, observed on Rainbow Agar, and reacts specifically with O157 antiserum
Confirmed	An isolate has *stx*, *eae*, and one or more of the target serogroup genes and has been biochemically confirmed to be *E. coli*.	Biochemically-identified *E. coli* isolate that is serologically or genetically determined to be ‘O157’ that meets at least one of the following criteria: 1) positive for Shiga toxin production, 2) positive for Shiga toxin gene, 3) genetically determined to be “H7”

Establishment Testing for non-O157 STEC

Many establishments that produce raw non-intact beef products, such as ground beef, incorporate antimicrobial interventions such as organic acid sprays in their processing. These methods should be effective in controlling non-O157 STEC. However, many firms will want to implement their own testing programs. A prudent establishment would use a test method that includes all hypothetical strains of *E. coli* O157:H7 and the target non-O157 STEC, typical or variant, that would be identified using FSIS' confirmatory testing procedures and criteria and that increases the likelihood of detecting low level contamination by these pathogens. FSIS recognizes that industry uses non-cultural methods that detect alternative target analytes for *E. coli* O157:H7 including, but not limited to, *eae* and *stx*. Establishments may increase the likelihood of detecting all hypothetical strains and low levels of contamination by these pathogens in a variety of ways, including but not limited to using a test method that is also used by a regulatory body or that is validated and certified by an independent body (i.e., AOAC, AFNOR, MicroVal, or NordVal). An establishment may also opt to use a test method that is subjected to a robust validation using the FSIS cultural method as a reference. Several companies have developed or are developing test kits to detect at least the six relevant STEC serogroups. Some kits have been submitted for review by validation bodies. In addition, some kits have been submitted for review by FSIS and have received "letters of no objection" from the Agency. FSIS continues to review other test kits submitted for review.

For establishment testing or testing on behalf of an establishment, FSIS recognizes that other criteria, while not used specifically by FSIS for identification of a non-O157 STEC, may be a significant and expedient indicator of the presence of non-O157 STEC in products. Such tests might be applied as rapid screening procedures to expedite analyses. If an establishment uses or contracts with a laboratory that uses such rapid screening procedures, and product is found positive by that test, FSIS expects the establishment to take appropriate corrective action and to ensure the proper disposition of adulterated products following a positive test result (9 CFR 417.3). The establishment will need to define and support the criteria it uses to define non-complying product.